

# BLANKROME

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ORDER

December 31, 2019

## VIA ECF

Honorable Kevin McNulty, U.S.D.J.  
United States District Court, District of New Jersey  
Martin Luther King Courthouse  
50 Walnut Street  
Newark, NJ 07101

**Re: In re: General Mills, Inc. Kix Cereal Litigation (2:12-cv-00249-KM-JBC)**  
**Letter Report re: Stay**

Dear Judge McNulty:

Pursuant to the Court's April 17, 2019 Order (ECF No. 218), Defendant General Mills Inc. ("General Mills") submits this letter to request that the Court continue the stay in this matter. As outlined below, the FDA recently communicated in September 2019 that it continues to work diligently regarding regulation of "natural" claims. This public assurance follows a string of statements from FDA representatives indicating that FDA's regulatory efforts surrounding use of the term "natural" are a key agency priority and that FDA will publicly communicate its position regarding regulation of "natural" soon. Taking into account this FDA activity and the effect of an FDA definition of "natural" on the outcome of this case, and because extending the stay will result in no prejudice to Plaintiffs, General Mills respectfully requests that the Court extend the existing stay until, at a minimum, June 30, 2020.

When the Court last addressed the existing stay in this matter in April 2019, the FDA's then Commissioner, Dr. Scott Gottlieb, had on numerous instances confirmed both to the public and, in at least one instance, to a member of Congress, that the FDA is actively engaged in regulatory proceedings regarding "natural," and views this issue as important. *See Letter From C. Sipos (March 28, 2019) (ECF No. 215) (citing FDA statements that potential regulation of the term "natural" is "an important matter for consumers and the food industry" and that "FDA is actively working to address [regulation of 'natural']").*<sup>1</sup>

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<sup>1</sup> Dr. Stephen M. Hahn was sworn as the new Commissioner of the FDA on December 17, 2019. *See United States FDA, Commissioner, available at* <https://www.fda.gov/about-fda/fda-commissioner>.

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Since that time, FDA representatives have continued to confirm that regulation of “natural” is forthcoming. Most recently, on September 27, 2019, the FDA held a public meeting at which Susan Mayne, the FDA’s Director of the Center for Food Safety and Applied Nutrition, addressed the status of FDA’s multi-year “Nutrition Innovation Strategy.” Director Mayne’s speech outlined the agency’s priorities and singled out the issue of “natural” claims as among the topics receiving particular agency attention. Director Mayne noted that the FDA was actively working on a proposed agency definition for the term “natural” (among other claims) explaining: “[W]e are close to proposing a new definition for the ‘Healthy’ claim on food labels and have been working diligently on the claim ‘Natural.’”<sup>2</sup>

Because FDA has again confirmed that regulation of “natural” is impending and continues to be the subject of agency attention and consideration, extending the pending stay remains the prudent and appropriate course of proceedings. As outlined in the Court’s prior orders, “the expertise of the FDA is critical” in resolving the issue presented in this litigation (i.e., use of the term “natural” in food products with ingredients made from crops grown from bioengineered seeds), and because plaintiffs’ requested relief is solely for retrospective damages, the case does present any “urgency” that would justify proceeding now without the benefit of the FDA’s considered views. *See* Order Staying Case (June 13, 2016) (ECF No. 205); *see also* Order Staying Case (October 6, 2016) (ECF No. 207); (Order Staying Case) (April 21, 2017) (ECF No. 209).

Moreover, staying this case while FDA proceedings remain pending is consistent with the approach taken by other courts. Many “natural” lawsuits remain stayed in deference to these agency proceedings. *See, e.g., Yu v. Dr. Pepper Snapple Group, Inc. et. al.*, 18-cv-6664 (N.D. Cal. June 18, 2019) (ECF No. 40) (entering stay through “the end of February 2020 without prejudice to a request to continue the stay”); *Rosillo v. Annie’s Homegrown*, 17-cv-2474 (N.D. Cal. Aug. 13, 2019) (ECF No. 57) (continuing stay and ordering parties to provide status update by January 31, 2020); *Campbell v. Annie’s Homegrown*, 17-cv-7288 (N.D. Cal. Aug. 13, 2019) (ECF No. 57) (same); *Stanton v. Sargento Foods*, 17-cv-2881 (N.D. Cal. Dec. 11, 2019) (ECF No. 60) (ordering that stay remain in place and setting status conference for March, 2020); *Holve v. McCormick & Co.*, 16-cv-6702 (W.D.N.Y. Nov. 6, 2019) (ECF No. 22) (continuing stay and ordering parties to submit joint status report by January 15, 2020); *Brazil v. Dole*, 12-cv-1831 (N.D. Cal. Oct. 17, 2017) (ECF No. 258) (case remains stayed and administratively closed); *Kane v. Chobani*, 12-cv-2425 (N.D. Cal. July 29, 2016) (ECF No. 182) (case remains stayed

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<sup>2</sup> Director Mayne’s remarks were posted publicly on the FDA’s website. *See* United States Food and Drug Administration, Remarks by Dr. Susan Mayne at the Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization (September 27, 2019), available at <https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-susan-mayne-public-meeting-horizontal-approaches-food-standards-identity-modernization>.

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pursuant to Ninth Circuit mandate).

For these reasons, General Mills respectfully requests that the Court order that the existing stay in this matter continue through June 30, 2020, with the parties to report to the Court in the interim any relevant updates in FDA proceedings that occur during that time.

Respectfully submitted,

/s/ Stephen M. Orlofsky

Stephen M. Orlofsky

SMO:

cc: All Counsel of Record (via ECF)

Ext to 6/30/2020

**SO ORDERED.**

  
**Kevin McNulty, U.S.D.J.**

**Date:**

1/7/2020